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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,027	IOUALALEN ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-27* is/are pending in the application.

4a) Of the above claim(s) *15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13,14 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks filed 13 February 2009 have been received and entered on the record. The Examiner acknowledges the following:

Claim 12 has been cancelled.

Claims 1-11, 13 and 14 have been amended. Claim 1 incorporates the cancelled limitation "[further] comprising an active constituent" of cancelled claim 12 as well as additional structure, size, constituent and temperature limitations. Claims 4-11, 13 and 14 have been amended to correct their improper dependencies. Claim 2 has been amended to remove the narrower limitation. Claims 5, 8-11, 13 and 14 have been amended in a similar manner. The remaining amendments are editorial.

Claims 21-27 have been added. Support for the claims is found in Applicant's originally submitted claims 2, 5, 7-10 and 14.

No new matter has been added.

Thus, claims 1-11, 13, 14 and 21-27 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Claims

Applicants' amendments to claims 4-11, 13 and 14, eliminating the improper dependencies, as discussed above, have been considered fully and are persuasive. Thus, said objections have been **withdrawn**.

Rejection under 35 USC 112

Applicants' amendments to claim 2, regarding the removal of the narrower of the two limitations within the claim, renders moot the rejections, under 35 USC 112, second paragraph. Thus, said rejection has been **withdrawn**.

Rejection under 35 USC 102(b)

Applicants' amendments, particularly those which are directed to claim 1, renders moot both of the rejections to claims 1-3, under 35 USC 102(b), as being anticipated by Blichare et al. (USPN 4,132,753) alone, as well as by Lantz et al. (USPN 3,146,167) alone. The amendment made to claim 1 incorporates the limitation from the cancelled claim 12 whereby the composition "further comprises an active constituent". Applicants' response states that the rejection is moot "because the claim now includes at least all the limitations of original claim 12, which is not included in the rejection". The Examiner respectfully submits that this amendment alone would not have been sufficient to overcome the rejections. Rather Applicants' amendment of the structural limitations, most notably the particle size, is sufficient to overcome the previous rejections. Thus, in view of the amendment, said rejections now stand **withdrawn**.

MAINTAINED OBJECTIONS/REJECTIONS

The following rejection is maintained from the previous Office Correspondence dated 15 October 2008 since the art which was previously cited continues to read on the amended limitations.

SPECIFICATION

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Applicants state in their response that a new Abstract was submitted which commences on a separate sheet. However, the Examiner respectfully submits that said amendment does not appear to have been submitted to the Office. Thus, said objection has been **maintained**.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blichare et al. (USPN 4,132,753) in combination with Lantz et al. (USPN 3,146,167).

The instant claims are directed to a system comprising spherical, hydrophobic particles wherein said particles comprise at least one hydrophobic wax, and at least one non-neutralized fatty acid. With regard to the limitation, wherein the system is solid at a temperature of up to 45°C, as recited in claim 2, until some material difference in the properties of the claimed composition are demonstrated distinguishing it from the art, said limitation is considered by the Examiner to be directed toward the instantly claimed composition.

The teachings to Blichare et al. are discussed above [*and are reproduced here for Applicants' convenience*].

Blichare et al. teach production of spherical, controlled-release granules comprising the active and a finely-divided wax-like material (claims 1 and 13). Said wax-like material is taught as consisting of waxes such as white beeswax, castor wax and Carnuba wax (claim 2). The wax-like material is also taught as comprising non-neutralized fatty acids such as myristic and stearic acids (claim 2).

Blichare further teaches in claim 1, that the melting point of the wax-like material is between about 30°C and about 100°C. Melting point temperature ranges for some of the wax-like material components are also taught (col. 3, lines 12-26).

The teachings to Lantz are also discussed above [*and are reproduced here for Applicants' convenience*].

Lantz et al. teach an oral pharmaceutical preparation having sustained release properties comprising solid substantially spherical lipid pellets having a solid medicament (claim 3). The sustained release or "time-delay" release material is taught as comprising admixed waxes such as Carnuba wax, beeswax and mineral wax, and fatty acids, such as stearic, lauric or myristic acids (col. 3, lines 41-51 and lines 58-60).

Lantz further advantageously teaches that the time-release or sustained release material will be solid at room temperature, but also has a low melting point of from 40°C to about 150°C (col. 3, lines 36-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a system of galenic (e.g. lipidic droplet) particles comprising at least one hydrophobic wax and at least one non-neutralized fatty acid, modify the proportions of the ingredients to attain the desired melting point temperature, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the inventions practiced by both Blichare et al. and Lantz et al. overlap in their teachings of solid, spherical-shaped, active-infused, pellet compositions whose release material is comprised of wax materials (e.g. Carnuba, bee and vegetable waxes) as well as overlapping fatty acids (e.g. stearic and myristic acids). Given the overlap in hydrophobic release materials, it then follows, absent any unexpected results that the materials also overlap in their respective melting points.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1-3 under 35 USC 103(a) over the combined teachings of Blichare et al. and Lantz et al. have been fully considered but they are not persuasive.

Applicants allege that the rejection is moot because the claims now include at least all of the limitations of cancelled claim 12, which is not included in the rejection.

In response, the Examiner respectfully submits that the amendment is not sufficient to overcome the rejection and respectfully points to claims 1 and 13 of the Blichare reference which are interpreted by the Examiner as continuing to read on the rejected claims.

Regarding the inclusion of an active constituent, more specifically one which is vacant from the surface of the lipidic particles, claim 1 teaches that the granules formed controllably release a medicament. During formation, the medicated granules are heated to a temperature which is higher than that of the wax carrier. When this happens, the heated medicament powder sinks into the molten surface (e.g. recedes from the surface) and the formulation is allowed to cool, thereby capturing the particles below the surface of the granule. Said amended limitation is thus anticipated.

Regarding the inclusion of a particle size limitation ranging between 0.5 to 1,500 microns, claim 1 to Blichare recites that the resulting medicated granules are sized to between 12 and 60 mesh, which when converted from "mesh size" to metric units, converts to a range of 1,680 micron- to 250 micron-sized particles. The Examiner respectfully directs Applicants to the included Mesh Conversion chart (http://www.showmegold.org/news/Mesh.htm). The size range which is taught does not anticipate that which is instantly recited by Applicants. However, the ranges do overlap significantly enough such that it would have motivated the skilled artisan at the time invention was made, to optimize the granule size in order to achieve that which is instantly claimed, absent evidence to the contrary (MPEP §2144.05).

Regarding the amended limitation whereby the particles of the galenic system comprise no water, surfactants, emulsifying agents, or traces of solvents, the Examiner respectfully points out that claim 1 of Blichare is silent to the inclusion of any of those compounds as constituents. The claim is directed to a particle comprising a powdered medicament and a wax-like material. Said limitation is thus anticipated.

Lastly, regarding the amended limitation whereby the instantly claimed particles have a melting temperature ranging between 15°C and 75°C, the Examiner respectfully submits that claim 1 of Blichare teaches that the medicament is embedded in a wax-like material whose melting temperature is between about 30°C and 100°C. The Examiner acknowledges that the melting temperature range which is taught does not anticipate that which is instantly recited by Applicants. However, the ranges do overlap significantly enough such that it would have motivated the skilled artisan at the time invention was made, to optimize the composition such that it employed a wax-like carrier material having a melting temperature within the range of the

instantly claimed 15°C to 75°C range (claim 1) as well as the further limited range of 15°C to 45°C (claim 2), in order to achieve that which is instantly claimed, absent evidence to the contrary (MPEP §2144.05).

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

NEW REJECTIONS

In light of Applicant's amendments, most notably to claim 1, as well as the newly added claims 21-27, the following rejections have been newly added:

CLAIM OBJECTIONS

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites a composition which comprises "at least one hydrophobic wax". Claim 6, which depends directly from claim 1, recites that the composition of claim 1 "further comprises at least one hydrophobic compound". The Examiner interprets claim 6 as not further limiting because the term "hydrophobic compound" is considered to be broader in scope than the term "hydrophobic wax". Furthermore, given that claim 1 already recites a composition which comprises at least one hydrophobic compound (e.g. wax), it is unclear to the Examiner how the composition does not already further include additional hydrophobic compounds.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Ioulalen et al. (USPN 6,572,892) and Blichare et al.

The '692 patent is the English publication of WO 99/65448, which was published 23 December 1999, but only in French.

The amended independent claim 1 is directed to a "galenic" system comprising hydrophobic solid lipid particles comprising at least one hydrophobic wax, at least one non-neutralized fatty acid and an active constituent which has been "eliminated from the surface" of said lipid particles (claim 1). Claim further limits the particles such that they a.) have a particle size between 0.5 and 1,500 microns, b.) contain no water, surfactants, emulsifying agents or traces of solvents, and c.) have a melting point between 15°C and 75°C. The term "galenic" is interpreted as defined by Applicants' instant disclosure as being synonymous with lipid-based

particles (see pg. 7, lines 9-12). Regarding the phrase "eliminated from the surface", the Examiner broadly and reasonably interprets the phrase as reciting a structural limitation whereby the active agent is not present at the surface of the composition. Claim 6 is interpreted as reciting the same subject matter as claim 1, as discussed above.

Ioulalen et al. teach a composition comprising a solid hydrophobic blend which contains no water, surface-active agents, or emulsifying agents, and which contains at least one hydrophobic wax, an oil and a cosmetic or pharmaceutical active principle (Abstract; claim 1). Said blend is taught as being a solid at room temperature and "in practice" the final blend is taught as having a melting temperature of 30°C (col. 4, lines 10-11). The final product is further taught as having a preferred bead-size ranging from 1 to 10,000 microns (Abstract). Ioulalen also teaches multiple techniques for producing said particles. However, none the methods expressly discuss the formation of a compound where the active constituent has been eliminated from the surface of the particle consists of dispersing the blend in a liquid which is not miscible (col. 4, line 66 to col. 5, line 5).

The teachings of claim 1 of Blichare expressly teach the formation of particles comprising a hydrophobic wax-like material and a powdered medicament, whereby the wax-like material is heated to a temperature which liquefies the wax-like material, but not the medicament. Once the wax-like material achieves a molten state, the powdered medicament "sinks" into the wax-like material (e.g. away from the surface of the particle). The particles are then cooled and the active captured inside the wax-like material.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the heating/cooling mixing method taught by Blichare into the method of Ioulalen in order to achieve the instantly claimed composition, particularly one which comprised no active constituent on the surface of the particles. The ordinarily skilled artisan would have been highly motivated to incorporate the method of Blichare particularly because both the inventions of Blichare and Ioulalen are drawn to producing hydrophobic wax-based microparticle compositions comprising an embedded active ingredient and because both practiced inventions employ methods which are highly similar, if not anticipatory of one another, for embedding said active within the hydrophobic carrier.

Based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

Claims 2-5, 8-11, 13, 14, 21, 22 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ioulalen et al. with respect to claim 1 as set forth above.

The amended independent claim 1 is directed to a "galenic" system comprising hydrophobic solid lipid particles, as discussed above.

Claim 2 is directed to a limitation whereby the composition of claim 1 is solid at a temperature of up to 45°C. Claim 13 recites the composition of claim 1 as having a melting temperature between 30°C and 45°C after incorporation of the active (i.e. the final blend). New

claim 21 recites that the composition of claim 1 is solid at a temperature of up to 37.5°C. Said limitations are expressly taught (col. 3, lines 11-15), wherein the final blend has a melting temperature between 15°C and 70°C and more preferably between 20°C and 45°C. The final blend is preferably taught as having a melting temperature of 30°C (col. 4, lines 10-12).

Claim 3 recites that the particles of the composition of claim 1 have a spherical form. Said limitation is expressly taught in that the compounds obtained in the invention of Ioulalen are shaped to give spherical hydrophobic particles called pearls (col. 4, lines 17-18).

Claim 4 further limits the hydrophobic wax of claim 1 to one which is vegetable-, animal- or mineral-based. Claim 8 recites specific types of animal-, and mineral-based waxes, whereas claim 24 recites more specific forms of vegetable-based waxes. Claims 5 and 22 recite that the composition of claim 1 comprises a weight percentage of wax ranging between 0.5 wt% and 99 wt% and between 1 wt% and 55 wt%, respectively. Ioulalen expressly teaches that the preferred wax compounds include: Carnuba, Candelilla, Alfa, ozokerite, beeswax, and vegetable oils such as olive, rice, jojoba and absolute flower waxes (col. 3, 21-31). The composition is further taught as comprising from 0.1% to 40% of the aforementioned waxes (col. 3, lines 21-22) and more preferably, the percent weight of hydrophobic waxes in the blend ranges from about 1 wt% to about 40 wt% (col. 4, lines 9-11).

Claim 7 recites that the melting point of the wax recited in claim 1 is between 15°C and 75°C, whereas new claim 23 recites a wax melting point temperature ranging between 30°C and 45°C. Ioulalen expressly teaches the use of palm tree oil, a species of palm oil, which in addition to teaching the limitations of claim 8, is further expressly taught as being part of a blend having melting point between 0° and 45°C (col. 49-55).

Claim 9 recites that the non-neutralized fat of claim 1 is comprised of fatty acids having linear chains ranging from 4-18 carbon atoms. Claim 25 further limits the fatty acids of claim 1 to myristic, lauric, palmitic or oleic acid. Claims 10 and 26 recite that the composition of claim 1 comprises a weight percentage of fatty acid ranging between 0.5 wt% and 75 wt% and between 1 wt% and 30 wt%, respectively. The above limitations are expressly taught in that the composition which is practiced by Ioulalen discusses using between 4% and 90% by weight of oily compounds such as sunflower oil. Sunflower oil is well known in the art as being composed of a variety of different fatty acids compounds including both palmitic and oleic fatty acids, as evidenced by Zimmerman et al. (*Journal of the American Oil Chemists' Society*; 1973).

Claim 11 further limits composition of claim such that the particle size is between 10 and 250 microns. Said limitation is expressly taught in the Abstract whereby particles of the practiced invention range from 1 to 10,000 microns.

Claims 14 and 27 recite that the composition of claim 13 wherein the capacity of the particles for holding the active ranges from between 0.02% and 75%, and 5% and 50%, by weight of the particles, respectively. The limitation recited by claims 14 and 17, which states "wherein the capacity of the particles for holding the active ranges from between…" is broadly and reasonably interpreted by the Examiner as reciting that "the particles comprise an amount of active agent ranging between…". The pearl formulations of the practiced invention are expressly taught as having a loading capacity for the active ingredient which ranges from 0.02% to 75% in relation to the pearl weight (col. 5, lines 55-57).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have prepared the instantly claimed hydrophobic solid lipidic particles. The ordinarily skilled artisan, under the guidance of the invention practiced by Ioulalen et al., would have been highly motivated to produce the instantly claimed particles and would have had an equally high expectation of successfully doing so, particularly since the reference anticipates, if not, expressly suggests compositions which embodied by the instantly claimed limitations. Therefore, absent evidence to the contrary, the invention as a whole was *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13, 21, 22, 24, 26 and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 14, 15, and 19 of

loulalen et al. (USPN 6,572,892). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to compositions which comprise solid lipid-based particles, both of which further comprise at least one hydrophobic wax or a blend of waxes, at least one fatty acid (e.g. plant oil; see claim 3 of '892), and at least one active constituent (see claim 15 of '892). The waxes recited by the instant claims 8 are also recited by claim 4 of the '892 patent. The instant claims 2 and 13 recite that the composition has a melting point ranging from 30°C -45°C, whereas claims 1 and 2 of the '892 patent respectively teach that the hydrophobic blend is solid at ambient (i.e. room temperature) and has a final melting temperature no greater than 70°C. The composition of the '892 patent is taught as being formed into sphere-shaped "pearls" (claim 7), which may range in size from 1-10,000 microns (claim 14). Lastly, claim 19 of the '892 patent teaches that the wax or wax-blend comprises 0.1% to 40% by weight of the composition. The key differences between the instant claims and the '892 patent are that the '892 patent does not expressly teach in its claims the melting point temperatures for the wax(es), the types of fatty acids and their weight percent ranges within the composition, or the specific types of vegetable oil recited by the instant claim 24.

CONCLUSION

Due to the new grounds of rejection, this action is deemed **non-final**.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615